

CLEAN COPY OF ALLOWED CLAIMS

20. A method for the preparation of a sterile Cetorelix lyophilizate, said method comprising the steps of

- (a) dissolving Cetorelix having the amino acid sequence of
AC-D-Nal(2)-D-pCl-Phe-D-Pal(3)-Ser-Tyr-D-Cit-Leu-Arg-Pro-D-Ala-NH₂
(SEQ ID NO: 1) in aqueous acetic acid to form a solution,
- (b) diluting said solution with water for injection,
- (c) adding bulking agent to the solution, wherein said solution has a pH range between 2.5-3.0, and
- (d) sterile filtering, dispensing into injection vials and lyophilizing the solution thereby obtaining a sterile Cetorelix lyophilizate.

21. The method according to claim 20, wherein the bulking agent used is a hexitol.

22. The method according to claim 21, wherein the hexitol is selected from the group consisting of mannitol, glucitol, sorbitol, D-sorbitol, dulcitol, allitol, iditol, urea or sodium chloride in an amount from 10-500 parts by weight per one part by weight Cetorelix.

23. The method according to claim 20, wherein 1 part by weight of cetorelix acetate is dissolved in 100-10,000 parts by weight of a 30% strength (w/w) acetic acid solution and diluted with water to 3% strength aqueous acetic acid, and wherein the bulking agent is mannitol.